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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/592,695	06/13/2000	Andrea G Cochran	P1762R1	7146
23552	7590	10/06/2003	EXAMINER	
MERCHANT & GOULD PC P.O. BOX 2903 MINNEAPOLIS, MN 55402-0903			WESSENDORF, TERESA D	
		ART UNIT	PAPER NUMBER	
		1639	34	
DATE MAILED: 10/06/2003				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)
	09/592,695	COCHRAN ET AL.
	Examiner T. D. Wessendorf	Art Unit 1639

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 25 July 2003.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-3,5-14 and 20-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-3,5-14 and 20-22 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>27,33</u> . | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Specification

The disclosure is objected to because of the following informalities: holes have been punched at the top of pages 2-3, 5, 10, 13 and 36. It is requested that applicants provide for substitute pages.

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors (typographical, grammatical and idiomatic). Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the claimed subgenus as recited in claim 20 wherein A2 and A4 are W or L. [This subgenus appears not to have support in the as-filed specification].

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 1-3 and 5-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite in the recitation that the "carboxy terminus of C1 is optionally protected with a carboxy protecting group and the amino terminus of C2 is optionally protected with an amino protecting group". The amino acid sequence of Seq. ID. 1 shows that the carboxy terminus of C1 is attached to A1. Therefore, it is not clear as to how it can be protected. [Cf. with claim 22].

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the

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examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-2, 4, 5, 8 and 9 are rejected under 35 U.S.C. 102(e) as being anticipated by Wrighton et al [5,830,851] for reasons stated in the last Office action.

Response to Arguments

Applicants argue that Wrighton et al does not disclose at least the element that each cyclized peptide in the library includes a sequence: C1-A1-A2-(A3)_n-A4-A5-C2. It is argued that the claims require all cyclized peptides in the library to comprise a specific set of amino acids where A1 and A5 must be W, Y, F, H, I, V or T and A2 and A4 must be W, Y, F, L, M, I, or V. The library of Wrighton is argued to contain peptides outside of this requirement. For example, positions A1 and A5 in the Wrighton library is said to be R, H, or L for A1 and D, E, I, L, or V for A5.

In response, A1 of the instant claim corresponds to X4 of Wrighton which is R, H, L, or W. The subgeneric formula of Wrighton with A1 defined as W, H and L together with the species included in the subgenus fully meets the claimed invention.

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If one of ordinary skill in the art is able to "at once envisage" the specific compound within the generic chemical formula, the compound is anticipated. One of ordinary skill in the art must be able to draw the structural formula or write the name of each of the compounds included in the generic formula before any of the compounds can be "at once envisaged." One may look to the preferred embodiments to determine which compounds can be anticipated. *In re Petering*, 301 F.2d 676, 133 USPQ 275 (CCPA 1962).

Applicants argue that in *In re Petering* the court found that the prior art anticipated the claims only because within the broad disclosure of the genus, the reference additionally disclosed specific preferences for five different substituent groups through a listing of preferred R groups and eight specific isoalloxazines. The court found that this disclosed subgenus of specific preferences contained only 20 compounds, and that one of skill in the art reading the reference, including the disclosed subgenus, would have at once envisaged the claimed compounds.

In reply, Wrighton discloses a specific species of the subgenus at col. 6, line 47. Thus, *In re Petering* is at point.

Applicants cite *In re Ultradent Products inc. v. Life-like Cosmetics Inc.*

In response, this case law appears inapplicable to the instant compound case. The instant application relates to

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subgenus-species compounds, not to the percentage range as argued.

Applicants argue that the peptide formulas disclosed in Wrighton et al comprise a very large number of possible peptides.

In reply, this is not as large as the claimed library especially, with the used of the open-ended word "comprising". The term encompasses all inconceivable insertions, deletions, substitutions and/or reactions of the different residues.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3, 5-10, 12-14 and 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wrighton et al (5,830,851) for reasons advanced in the last Office action.

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Response to Arguments

Applicants argue that Wrighton et al does not disclose at least the element that each cyclized peptide in the library includes a sequence: C1-A1-A2-(A3)_n-A4-A5-C2. It is argued that the claims require all cyclized peptides in the library to comprise a specific set of amino acids where A1 and A5 must be W, Y, F, H, I, V or T and A2 and A4 must be W, Y, F, L, M, I, or V. The library of Wrighton is argued to contain peptides outside of this requirement. But admit that that in Wrighton, the positions analogous to A1 and A5 in the Wrighton library, A1 must be R, H, or L or W; A5 must be D, E, I, L, or V.

In response, A1 of the instant claim corresponds to X4 of Wrighton which is R, H, L, or W. The subgeneric formula of Wrighton with A1 defined as W, H and L together with the species included in the subgenus renders the claimed *prima facie* obvious to one of ordinary skill in the art. It is readily apparent from the disclosure of Wrighton that one having ordinary skill in the art can pick and chose amino acid residues from the library of Wrighton to arrive at the instant claimed invention.

It is further argued that Wrighton does not teach or suggest that their library can accommodate a variety of peptide structures other than GPXT.

In reply, just because Wrighton is silent with respect to accommodating a variety of peptide does not indicate that Wrighton does not teach or at least would suggest such.

It is further argued that Wright does not teach the positions that provide for increased stability of the hairpin structures in solution.

In response, applicants' arguments are not commensurate in scope with the claims. The claims do not recite the argued increased stability. Nevertheless, it would be within the ordinary skill in the art to determine such property given a known peptide sequence using known techniques as stated in the specification.

Claims 1-3, 5-10, 12-14 and 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over McLafferty et al (Gene).

McLafferty discloses a phage library as shown at page 30, Table 1, specifically the first six peptides in the last row of peptides e.g., HPQ 6.1. The specific library of McLafferty renders obvious the broad claimed peptides. Applicants' used of the word "comprising" does not preclude the presence of other amino acid residues present in the prior art peptide i.e., the indels (insertions, deletions and substitutions). It has been long held that the use of the term "comprising" leaves a claim

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open for inclusion of materials or steps other than those recited in the claims". Ex parte Davis, 80 USPQ 448.

Conclusion

Claim 11 is free of prior art and would be allowable when incorporated into claim 1.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (703) 308-3967. The examiner can normally be reached on Flexitime.

The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-7924 for regular communications and (703) 308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

T.D. W
T. D. Wessendorf
Primary Examiner
Art Unit 1627

tdw
September 30, 2003